



300.1012

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Xiu Xiu Cheng, et al.
Serial No.: 09/705,625
Filed: November 3, 2000
For: **Methods for Treating Diabetes Via
Administration Of Controlled Release
Metformin**
Examiner: T. Ware Art Unit: 1615

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

February 28, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants note that reference AM is being submitted in an envelope labeled "PROPRIETARY MATERIAL NOT OPEN TO PUBLIC. TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED U.S. PATENT AND TRADEMARK OFFICE EMPLOYEE." as this material in the envelope is considered proprietary and is being submitted for consideration under MPEP §724 (8th Edition).

The biostudy (which resulted in the data submitted as reference AM) was performed using formulations prepared in accordance with U.S. Patent No. 6,099,859. It is noted that the exemplified formulations did not provide a T_{\max} between 8-12 hours except when the formulation prepared in accordance with Example 3 was administered at dinner. As set forth in the accompanying biostudy data, the mean T_{\max} values for the Examples of the '859 were as follows: Example 1 (fasting) 4.67 hours (*See, e.g.*, pages 1 and 3 of the biostudy); Example 2 (fasting) 4.33 hours (*See, e.g.*, pages 10 and 12 of the biostudy); Example 2 (fed a.m.) 6.80 hours (*See, e.g.*, pages 13, 14 and 16 of the biostudy); Example 3 (fed a.m.) 6.67 hours (*See, e.g.*, pages 4 and 6 the biostudy); Example 3 (Fed p.m.) 9.67 hours (*See, e.g.*, pages 17 and 20 of the biostudy). Therefore, the only instance that the T_{\max} was between 8-12 hours was Example 3 fed in the P.M. (at dinner).

In addition, pages 2, 5, 11, 15, 19 of the biostudy data includes plasma concentration v. time graphs and data for formulations prepared in accordance with Examples 1(fasting), 3 (fed), 2 (fasting), 2 (fed), and 3 (fed), respectively, of U.S. Patent No. 6,099,859; pages 8 and 9 of the biostudy data include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 2 (fasting and fed) and Example 3 (fed a.m. and p.m.) of U.S. Patent No. 6,099,859; and pages 7 and 18 include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 3 (fed a.m. and p.m.) of U.S. Patent No. 6,099,859.

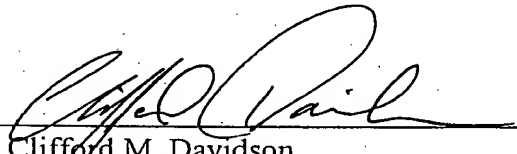


300.1012

This Information Disclosure Statement is being filed after a First Office Action but before a Final Office Action or Notice of Allowance. Pursuant to 37 C.F.R. § 1.98(c), a check for \$180.00 is enclosed to cover the required fee. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
Clifford M. Davidson
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FORM PTO-144
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
300.1012SERIAL NO.:
09/705,625

PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Xiu Xiu CHENG, et al.

FILING DATE:
November 3, 2000GROUP:
1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6	4	7	5	5	2	1	11/05/2002	Timmins et al.	424	469	Sep. 16, 1999
	AB												
	AC												
	AD												
	AE												
	AF												
	AG												

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AH													
	AI													
	AJ													
	AK													
	AL													

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	Andrx Pilot Biostudy Data (20 pages)
	AN	
	AO	
	AP	
	AQ	
	AR	
	AS	

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



300.1012

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: To Be Assigned	Art Unit: 1614
Re: Application of:	Chih-Ming CHEN, et al.
Serial No.:	09/705,625
Filed:	November 3, 2000
For:	METHODS FOR TREATING DIABETES VIA ADMINISTRATION OF CONTROLLED RELEASE METFORMIN

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

September 17, 2001

S i r:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying PTO-1449 Form for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due.

I hereby certify that the documents referred to as attached therein and/or fee are being deposited with the United States Postal Service with sufficient postage as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on September 17, 2001.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:

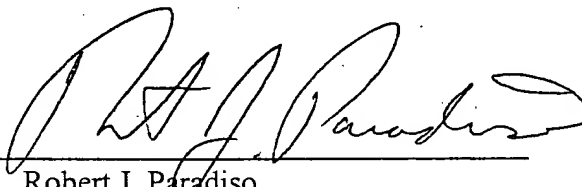
However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the references cited on the accompanying PTO Form-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

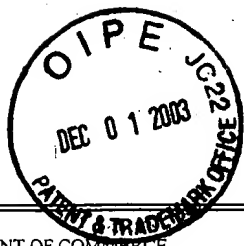
It is respectfully submitted that the pending claims are patentable over all the references made of record at this time.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

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FORM PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE										ATTY. DOCKET NO. 300.1012		SERIAL NO. 09/705,625	
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)										APPLICANTS Chih-Ming CHEN, et al.			
										FILING DATE November 3, 2000		GROUP 1614	

U.S. PATENT DOCUMENTS														
EXAMINER INITIAL										DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	6	0	1	0	7	1	8		1/4/00	Al-Razzak et al.	424	464	
	AB	5	8	5	8	3	9	8		1/12/99	Cho	424	450	
	AC	5	6	9	1	3	8	6		11/25/97	Inman et al.	514	691	
	AD	5	6	8	8	5	1	8		11/18/97	Ayer et al.	424	422	
	AE	5	6	7	4	9	0	0		10/7/97	Ubillas et al.	514	557	
	AF	5	6	6	8	1	1	7		9/16/97	Shapiro	514	55	
	AG	5	6	6	7	8	0	4		9/16/97	Wong et al.	424	472	
	AH	5	6	5	0	1	7	0		7/22/97	Wright et al.	424	473	
	AI	5	6	3	1	2	2	4		5/20/97	Efendic et al.	514	12	
	AJ	5	6	2	9	3	1	9		5/13/97	Luo et al.	514	284	

FOREIGN PATENT DOCUMENTS															
										DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
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	AK	9	9	4	7	1	2	8		9/23/99	WO	A61K	9/24		
	AL	9	9	4	7	1	2	5		9/23/99	WO	A61K	9/20		
	AM	9	9	2	9	3	1	4		6/17/99	WO	A61K	31/155		
	AN	9	6	0	8	2	4	3		3/21/96	WO	A61K	31/155		

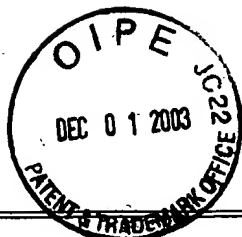
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AO	<i>Physicians' Desk Reference</i> (54 th Ed. 2000), pp. 831-835.
	AP	Sheen, Andre J., Clinical Pharmacokinetics of Metformin, <i>Clinical Pharmacokinetics</i> , May 30, 1996, 5:359-371.
	AQ	Bailey, Clifford J., et al., Metformin, <i>The New England Journal of Medicine</i> , Feb. 29, 1996, 334:574-579.
	AR	Dunn, Christopher J., et al., Metformin: A Review of its Pharmacological Properties and Therapeutic Use in Non-Insulin-Dependent Diabetes Mellitus, <i>Drugs</i> (1995), 49:721-747.
	AS	Karttunen, P., et al., The Pharmacokinetics of Metformin: A Comparison of the Properties of a Rapid-Release and a Sustained-Release Preparation, pp. 31-36.

EXAMINER	DATE CONSIDERED
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 300.1012		SERIAL NO. 09/705,625							
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				APPLICANTS Chih-Ming CHEN, et al.									
				FILING DATE November 3, 20000		GROUP 1614							
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL									DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	BA	5	6	1	4	5	7	8	3/25/97	Dong et al.	524	377	
	BB	5	5	9	1	4	5	4	1/7/97	Kuczynski et al.	424	486	
	BC	5	5	4	5	4	1	3	8/13/96	Kuczynski et al.	424	473	
	BD	5	5	4	3	1	5	6	8/6/96	Roorda et al.	424	484	
	BE	5	5	1	2	2	9	3	4/30/96	Landrau et al.	424	449	
	BF	5	4	1	3	5	7	2	5/9/95	Wong et al.	604	892.1	
	BG	5	3	0	8	3	4	8	5/3/94	Balaban et al.	604	892.1	
	BH	5	1	8	5	1	5	8	2/9/93	Ayer et al.	424	473	
	BI	5	1	7	8	8	6	7	1/12/93	Guittard et al.	424	473	
	BJ	5	1	4	1	7	5	2	8/25/92	Ayer et al.	424	473	
	BK	5	1	2	0	5	4	8	6/9/92	McClelland et al.	424	473	
	BL	5	1	1	0	5	9	7	5/5/92	Wong et al.	424	438	
	BM	5	0	9	1	1	9	0	2/25/92	Kuczynski et al.	424	473	
	BN	5	0	7	1	6	0	7	12/10/91	Ayer et al.	264	112	
	BO	5	0	2	4	8	4	3	6/18/91	Kuczynski et al.	514	255.06	
	BP	4	9	6	3	1	4	1	10/16/90	Eckenhoff	604	892.1	
	BQ	4	8	9	2	7	3	9	1/9/90	Shah et al.	424	473	
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FOREIGN PATENT DOCUMENTS													
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FORM PTO-1449 (REV. 7-80)										U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			ATTY. DOCKET NO. 300.1012		SERIAL NO. 09/705,625	
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)										APPLICANTS: Chih-Ming CHEN, et al.						
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	CA	4	8	5	1	2	2	9	7/25/89	Magruder et al.	424	457				
	CB	4	7	8	3	3	3	7	11/8/88	Wong et al.	424	468				
	CC	4	7	7	7	0	4	9	10/11/88	Magruder et al.	424	457				
	CD	4	7	0	4	1	1	8	11/3/87	Eckenhoff	424	438				
	CE	4	6	9	2	3	3	6	9/8/87	Eckenhoff et al.	424	468				
	CF	4	6	2	7	8	5	0	12/9/86	Deters et al.	604	892.1				
	CG	4	6	2	4	8	4	7	11/25/86	Ayer et al.	424	467				
	CH	4	6	1	5	6	9	8	10/7/86	Guittard et al.	604	892.1				
	CI	4	6	1	2	0	0	8	9/16/86	Wong et al.	604	892.1				
	CJ	4	6	0	9	3	7	4	9/2/86	Ayer	424	473				
	CK	4	5	8	7	1	1	7	5/6/86	Edgren et al.	424	473				
	CL	4	5	2	2	6	2	5	6/11/85	Edgren	424	473				
	CM	4	1	1	1	2	0	1	9/5/78	Theeuwes	424	473				
	CN	4	0	8	8	8	6	4	5/9/78	Theeuwes et al.	219	121.71				
	CO	4	0	8	0	4	7	2	3/21/78	Bohuon	514	555				
	CP	4	0	7	7	4	0	7	3/7/78	Theeuwes et al.	424	427				
	CQ	4	0	6	3	0	6	4	12/13/77	Saunders et al.	219	121.7				
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		DC		4		0		0		8		7		1		4		2/22/77		Theeuwes et al.		424		427																																			
		DD		3		9		5		7		8		5		3		5/18/76		Bohuon		560		143																																			
		DF		3		9		5		2		7		4		1		4/27/76		Baker		424		405																																			
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